REMARKS/ARGUMENTS

Claims 2-5, 11-22 and 24-32 are pending in the current application. Claims 2-5, 11-15, 20-22 and 24 were examined. Claims 16-19 and 25-32 were withdrawn as being drawn to nonelected inventions.

Double Patenting

The prior provisional rejection of claims 2-3, 12-15 and 24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 27, 28, 30-35 and 40 of copending Application No. 10/533,462 was maintained. Applicants note that this is a provisional rejection. At the time a patent issues Applicants will file a terminal disclaimer should issued claims still sustain an obviousness rejection.

The prior provisional rejection of claims 2, 3 and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 34 and 36-41 of copending Application No: 11/587,023 was maintained. Applicants note that this is a provisional rejection. At the time a patent issues Applicants will file a terminal disclaimer should issued claims still sustain an obviousness rejection.

Claim Rejection – 35 USC § 103

The prior rejection of Claims 1-15, 20-22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Boutriau *et al.* (WO 02/00249 A2), Kurikka *et al.* (Journal of Pediatrics, 1996), Truong-Le, Vu (US 7,135,180 B2) and Volkin *et al.* (US 6,051,238) was maintained. Applicants respectfully traverse this rejection.

Claims 1 and 6-10 were cancelled in the previous response on August 22, 2008. Therefore, this rejection is moot as to the cancelled claims.

The Examiner has not established a *prima facie* case of obviousness for at least the reason that the Examiner has failed to establish a rational underpinning to support the legal conclusion of obviousness.

The Supreme Court has stated that the *Graham* factors continue to define the inquiry that controls in determining if the claimed subject matter is obvious under

§ 103. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.* (550 U.S. ___, 127 S. Ct. 1727, 2007, 82 USPQ2d 1385, 1396, (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)). The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. M.P.E.P. § 2142.

The Examiner alleges in the April 29, 2008 Action that

> It would have been obvious to one of ordinary skill in the art to modify the compositions taught by Boutriau et al. and Kurikka et al. in order to provide a dried multi-valent vaccine of IPV and bacterial saccharides as a foamed glass composition with a stabilizing agent. One would have been motivated to do so, given the suggestion by Boutriau et al. and Kurikka et al., that the compositions be modified in order to incorporate the various antigens of interest into a stable vaccine composition with sucrose, a stabilizing agent followed by lyophilization and that compositions such as that claimed be utilized in simultaneous vaccinations, respectively.

(page 6, Office Action dated April 29, 2008).

The Examiner has not provided a rational underpinning to support this legal conclusion. The Examiner has not provided any support for the alleged suggestion by Boutriau *et al.* or Kurikka *et al.*. There is no recitation of a page or line number from either Boutriau *et al.* or Kurikka *et al.* to support this alleged suggestion.

Applicants' representative has searched Boutriau *et al.* and the only reference to sucrose identified was in the Examples comprising conjugates of *N. meningitidis* and *H. influenzae* capsular polysaccharides. These examples did not contain IPV. The only noted reference to IPV in Boutriau *et al.* is in a list of additional components which may be part of the final immunogenic composition. (page 3, lines 23-33). There is no teaching of drying IPV, as acknowledged by the Examiner on page 5 of the Office Action dated April 29, 2008. Furthermore, Boutriau *et al.* discuss mixing separate components of their vaccine composition in 2 containers, one containing components in liquid form and a second containing components in lyophilized form. (page 5, lines 18-25). There is no suggestion to modify components which are

traditionally administered in liquid form to administer them in lyophilized form. Therefore, the Examiner has not provided a rationale underpinning for the allegation that, "It would have been obvious to one of ordinary skill in the art to modify the compositions taught by Boutriau et al. and Kurikka et al. in order to provide a dried multi-valent vaccine of IPV and bacterial saccharides as a foamed glass composition with a stabilizing agent. One would have been motivated to do so, given the suggestion by Boutriau et al. ...that the compositions be modified in order to incorporate the various antigens of interest into a stable vaccine composition with sucrose, a stabilizing agent[,] followed by lyophilization." (page 6, Office Action dated April 29, 2008). As acknowledged by the Examiner, Boutriau *et al.* fail to teach "the specific drying of IPV with a stabilizing agent and a bacterial saccharide or the addition of phenol red." (page 5, Office Action dated April 29, 2008).

As indicated in Applicants' specification, at the date of filing, "no successful example of making a dried solid vaccine formulation of IPV that retains a high degree of antigenicity and/or immunogenicity has been reported." (page 3, lines 6-7). "IPV is well known as a component of vaccines, however, it is formulated as a liquid, for example in Infanrix penta ®. The process of freeze-drying IPV has been associated with the loss of antigenicity so that it is difficult to formulate an effective vaccine comprising a dried form of IPV." (page 1, lines 15-18, Applicants' specification).

Applicants' representative has also searched Kurikka *et al.* and has been unable to find support for the Examiner's assertion that "compositions such as that claimed [can] be utilized in simultaneous vaccinations." (page 6, Office Action dated April 29, 2008). In contrast, Kurikka *et al.* relates to seroresponses to five different vaccine schedules for *Haemophilus influenzae* type b (Hib)-tetantus toxoid conjugate vaccine in infants. The IPV administered by Kurikka *et al.* in a separate immunogenic composition was not dried, but was instead a monovalent IPV vaccine available in liquid form. Therefore, there is no rationale underpinning for the Examiner's allegation that "compositions such as that claimed [can] be utilized in simultaneous vaccinations." (page 6, Office Action dated April 29, 2008). The Examiner acknowledges that "Kurikka *et al.* do not teach the lyophilization or stabilizing of the vaccines as a foamed glass composition of the combined antigens in

a vaccine, in a container with a water repellent inner surface." (page 5, Office Action dated April 29, 2008).

Truong-Le, Vu does not make up for the deficiencies of Boutriau *et al.* and Kurikka *et al.* Truong-Le, Vu only provides "methods and compositions to preserve bioactive materials in a dried foam matrix." (abstract). It does not suggest preserving IPV. (column 14, lines 27-32). Although the Examiner states that Truong-Le can be applied to IPV (page 7, Office Action dated April 29, 2008), he does so using impermissible hindsight. One of ordinary skill in the art would have no reasonable expectation of success that drying IPV would yield a desirable immunogenic composition. As discussed above, the process of freeze-drying IPV had been associated with the loss of antigenicity. Therefore, Truong-Le, Vu also fail to disclose an immunogenic composition comprising inactivated polio virus (IPV), a capsular polysaccharide or oligosaccharide antigen from *Haemophilus influenzae* b, and a stabilizing agent, all formulated as a dried composition, which after reconstitution is capable of generating an immune response against polio virus, as recited in independent Claim 2. There would not have been a reasonable expectation of success of obtaining Applicants' immunogenic composition based on the knowledge of one of ordinary skill of in the art.

Volkin *et al.* fail to make up for the deficiencies of Boutriau *et al.*, Kurikka *et al.* and Truong-Le, Vu. Volkin *et al.* also fail to teach a dried composition comprising IPV. They do not teach a composition further comprising a capsular polysaccharide or oligosaccharide antigen from *Haemophilus influenzae* b, and a stabilizing agent, all formulated as a dried composition, which after reconstitution is capable of generating an immune response against polio virus, as recited in independent Claim 2.

The Examiner has not established a *prima facie* case of obviousness for at least the reason that the Examiner has failed to establish a rational underpinning to support the legal conclusion of obviousness.

Applicants respectfully submit that independent Claim 2 is patentable over Boutriau *et al.*, Kurikka *et al.*, Truong-Le, Vu and Volkin *et al.* Pending Claims 3-5,

11- 15, 20-22 and 24 depend either directly or indirectly from patentable Claim 1. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Should any outstanding issues remain, the Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted:

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